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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/060,022	01/28/2002	William E. Sonnier	forbes-pitchextr	4919

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EXAMINER	
BADIO, BARBARA P	

ART UNIT	PAPER NUMBER
1628	

MAIL DATE	DELIVERY MODE
01/14/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/060,022	SONNIER ET AL.	
	Examiner	Art Unit	
	Barbara P. Badio	1628	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/17/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

First Office Action on the Merits of a RCE

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 17, 2009 has been entered.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Status of the Application

3. Claims 1-19 are pending in the present application and are rejected as indicated below.

Claim Rejections - 35 USC § 103

4. The rejection of claims 1-19 under 35 USC 103(a) over Wong et al. (WO 99/42471) is maintained.

Applicant argues the applicant was first to discover that predistillation of tall oil pitch to remove volatile acidic components is critical to the economic viability of the

process and, there is neither teaching, suggestion, nor motivation in Wong for said economically critical steps. Applicant's argument was considered but not persuasive for the following reasons.

The issue is not whether the reference teaches or suggests the economic value of predistillation of the tall oil pitch. The issue is whether said distillation would have been obvious to the skilled artisan in the art at the time of the present invention.

As noted in the previous Office Action dated November 18, 2008, the reference teaches preliminary distillation of crude tall oil to obtain a depitched tall oil, containing fatty and rosin acids, and a tall oil pitch, containing a small amount of fatty and rosin acids. Additional purification of tall oil pitch for use as starting material in the prior art process in order to improve the purification of the end product would have been obvious to the skilled artisan in the art at the time of the present invention.

Applicant also argues further distinctions including the separation period and crystallization solvents. Again, as noted in the Office Action dated November 18, 2008, workup procedure(s) is not a patentable distinction absence a showing of criticality. Additionally, the use of solvents, such as, ketones, hydrocarbons etc, for crystallization of sterols are well known in the art (see page, lines 1-14 of the cited reference; page 8, line 20 – page 9, line 8 of the present specification; page 6, 2nd paragraph of the Office Action dated November 18, 2008).

In summary, the further purification of tall oil pitch for use as starting material in the prior art process as well as the use of crystallization solvents known in the art are

prima facie obvious based on the teachings of the prior art and the level of skill of the ordinary artisan in the art at the time of the present invention.

For these reasons and those given in the previous Office Action, the rejection of claims 1-19 under 35 USC 103(a) over Wong et al. (WO 99/42471) is maintained.

5. Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wong et al. (WO 99/42471) in view of Hamunen et al. (US 7,371,876).

Wong et al. teaches a process for the preparation of phytosterols from tall oil pitch (see page 8, line 21 - page 9, line 18 of the present specification; see the entire article, especially page 3, line 22 - page 7, line 20). The process comprises (a) saponifying the steryl esters in the pitch to free phytosterol by the use of a water solution of an alkali metal base, such as sodium hydroxide, potassium hydroxide or a combination thereof at a temperature of 100 to 250°C for a period of 1 to 5 hours (see page 4, line 18 - page 5, line 22); (b) neutralizing the saponified pitch by the addition of sufficient acid, such as an organic acid, i.e., acetic acid or formic acid, or a mineral acid, i.e., sulphuric acid, hydrochloric acid or phosphoric acid, to reach a water pH between 4 and 7 (see page 5, line 23 - page 6, line 7); (c) maintaining the mixture at a temperature of 10 to 100°C for a period of 1 to 10 hours to effect the disengagement of water from the organic phase; (e) removing the excess water and heating the obtained organic phase to remove any additional water to form a modified pitch (see page 9, lines 9-18); (f) the modified pitch is introduced into an ultra-low press evaporator operating in the range of 0.1 to 10 millibars pressure and a temperature of 160 to 280°C for the removal

of the light ends (see page 6, lines 19-23); (e) distilling the bottom fraction of the modified pitch containing the free phytosterols in a second ultra-low pressure wiped film evaporator operating at a pressure of 0.01 to 1.0 millibars pressure and a temperature of 180 to 300°C obtaining a light phase distillate (see page 7, line 24 - page 7, line 5); (f) dissolving said light phase distillate obtained in a solvent, such as monohydric alcohol, i.e., methanol, ethanol, 2-propanol or combination thereof (see page 7, lines 6- 12); (g) cooling the mixture obtained to produce a slurry with phytosterols crystallized therein (see page 7, lines 13-16) and (h) washing and filtering to dryness the slurry (see page 7, lines 17-20). Wong teaches the use of wiped film evaporators and the recycling and reuse of the filtrate obtained after recovery of the pure phytosterol crystals (see Examples 2 and 4; page 7, lines 18-20).

The instant claims differ from the reference by reciting a preliminary distillation step of the tall oil pitch. However, the reference teaches a preliminary distillation of crude tall oil to obtain a depitched tall oil, containing fatty and rosin acids, and a tall oil pitch, containing a small amount of fatty and rosin acids and a substantial amount of the original unsaponifiables. Based on the level of skill of the ordinary artisan in the chemical art and the teaching of the art of the initial purification of the starting crude tall oil, further purification by distillation of the obtained tall oil pitch would be obvious. The motivation to further purify the starting material, i.e., tall oil pitch, is based on the desire to improve the purity the end product.

The claimed invention differ from the reference by reciting (a) an acid value of less than 30/40 (claims 2 and 3); (b) the occurrence of steps c) and d) in the same

reaction vessel (claim 8); (d) vigorous agitation in step d) (claim 9); (c) step e) is carried out without agitation; (d) an additional phase separation of the water phase obtained after step e) and (e) the use of ketones, hydrocarbons or mixture thereof in step i).

The acid value of the starting material is dependent on the amount of acid, i.e., fatty and rosin acids, therein. Obtaining said acid value would require only routine experimentation which is well within the level of skill of the ordinary artisan. The motivation to obtain a lower acid value would be based on the desire to obtain a purer material for saponification.

Performing an additional phase separation of the water phase is also prima facie obvious to the skilled artisan. The motivation would be the removal of any of the desired product that might be present in the water phase in order to increase the yield of the end product.

The art, as shown by Hamunen et al. ('876) teaches various solvents/solvent systems for crystallization of sterols which is inclusive of alcohols, ketones, hydrocarbons or mixture thereof (see for example, col. 1, lines 46-50). Based on the level of skill of the ordinary art at the time of present invention, the utilization of a ketone or a hydrocarbon or a mixture thereof instead of an alcohol in the crystallization of the sterols as taught by Wong would have been prima facie obvious.

Lastly, the workup procedure(s), such as the use of different distillation columns or the use of the same vessel for multiple steps, is not a patentable distinction absence a showing of the criticality of said variation since said is well within the level of skill of

the ordinary artisan in the art.

Telephone Inquiry

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brandon Fetterolf can be reached on 571-272-2919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Barbara P. Badio/
Primary Examiner, Art Unit 1628